

RESPONSE TO FINAL OFFICE
ACTION DATED FEBRUARY 3, 2004

Appln. No. 09/998,878

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REMARKS

This is in response to the Office Action dated February 2, 2004. Reconsideration is respectfully requested.

Request for Extension of Time

Applicant requests that the period for response be extended three months, from May 2, 2004 to August 2, 2004. Enclosed is a check in the amount of \$475 to cover the three-month extension fee pursuant to 37 CFR 1.17(a)(3).

Canceled Claims

Claims 18-30 are canceled without prejudice in view of the finality of the restriction.

Summary of Rejections

Claims 1-17 are pending. Claims 3, 4, 11 and 12 are rejected under 35 USC 112, second paragraph, as being indefinite. Applicant has amended Claim 3 to eliminate the term "nitinol", substituting therefore "nickel-titanium alloy" which is the generic term for nitinol. This eliminates any indefiniteness for both Claim 3 and Claim 4, which is dependent upon Claim 3. Applicant will amend the specification respecting the trademark names should allowable subject matter be found in the claims.

Claim 11 is amended by the elimination of the recitation of "third filamentary members" and the comma that appears on line 5 of the claim, which is the source of the ambiguity perceived by the Examiner. Applicant means that the second filamentary members visually identify the attachment region. Claim 12, depending from Claim 11, is also thereby no longer indefinite.

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Claims 1-4 and 7 are rejected as anticipated by International Patent Publication WO 99/21506 to Jayaraman. Claims 1 and 8-12 are rejected as anticipated by European Patent Application EP 0 938 878 to Rakos et al. Claims 1, 5, 6, 16 and 17 are rejected as anticipated by U.S. Patent No. 4,047,252 to Liebig et al. Claims 1, 8-10 and 13-15 are rejected as obvious over U.S. Patent No. 6,287,335 to Drasler et al in view of Jayaraman.

Summary of the Invention

New independent Claim 31 recites a graft for repair of living animal tissue. The graft comprises a substrate having an edge and formed from a plurality of interlaced first filamentary members 12. The substrate thus described is shown by way of example in Figure 1 of the application. The graft further comprises a reinforced attachment region 14 confined to a position adjacent to an edge 16 of the substrate. The attachment region 14 is defined by a pair of second filamentary members 20 that are positioned in spaced relation adjacent to one another. The filamentary members 20 have a higher tensile strength than the filamentary members 12 forming the substrate.

By confining the attachment region 14 to a position adjacent to an edge of the substrate, applicant secures the following advantages. The use of the higher strength filamentary members 20 is limited to only the attachment regions 14, positioning the members 20 where they will be most effective and thereby saving cost of material as these members are usually more expensive than the filamentary members 12 forming the substrate. The bulk and flexibility of the substrate is not significantly increased, as would occur if the filamentary members 20 were used throughout the entire substrate, the higher strength members generally having greater diameters and higher stiffness concomitant with their

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higher strength. Lower bulk and higher flexibility mean that the substrate according to the invention can be delivered subcutaneously through relatively smaller catheters as compared with other grafts. The filamentary members 20 furthermore unambiguously define the attachment region where sutures or other attachment means may be used, eliminating any guesswork or confusion on the part of the surgeon.

Applicant respectfully traverses the rejections of the claims as explained in the arguments presented below.

The Argument

Independent Claim 31 recites a graft comprising a substrate and having a reinforced attachment region defined by a pair of higher tensile strength filamentary members, the reinforced attachment region being confined to a position on the substrate adjacent to an edge of the substrate. None of the cited references teaches or suggests this arrangement.

Jayarman discloses a wire reinforced fabric stent wherein the reinforcing wires are distributed uniformly throughout the fabric. There is no teaching of a reinforced attachment region confined adjacent to an edge of the stent anywhere in the description or drawings of Jayarman. The reinforcing wires in Jayarman extend helically around a fabric cylinder and clearly do not reinforce either end of the cylinder where it would be attached, for example by sutures, to repair tissue. Furthermore, items made according to the teachings of Jayarman would not secure any of the advantages of lower cost, greater flexibility and lower bulk precisely because the reinforcing wires are distributed throughout the entire stent, and not confined adjacent to an edge as recited in the claim. Clearly Jayarman does not anticipate Claim 31 as it teaches none of the elements of the claim and a graft constructed

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according to Jayarman's teachings could not function as intended by the applicant.

Similarly, Rakos et al discloses a wire reinforced vascular prosthesis. Again, as shown in the figures, the reinforcing elements are distributed throughout the structure of the prosthesis, and there is no teaching or suggestion of a reinforced attachment region confined adjacent to an edge where it will be most effective. Rakos et al secures none of the aforementioned advantages of cost reduction, flexibility or compactness associated with applicant's invention.

Liebig et al is not relevant to applicant's invention because it does not teach any form of reinforcement or attachment for a fabric structure, let alone a reinforced region confined adjacent to an edge of the fabric. Liebig et al does teach use of a double ply yarn at column 4, line 15, but the double ply yarn is used for loops that extend outwardly from the fabric. The loops cannot reinforce the fabric or provide an attachment region as recited in applicant's claims.

The combination of Drasler et al and Jayarman cannot properly support a rejection of applicant's claims on the basis of obviousness because neither reference teaches a graft having a reinforced attachment region confined adjacent to an edge. Both references teach distributing higher strength filaments throughout the entire fabric structure. This is clearly a teaching away from applicant's invention, wherein the advantages of the invention are secured specifically by not distributing the higher strength filaments throughout the entire substrate, but by concentrating and confining them to a location where they will be most effective. Where there is a teaching away, there is no motivation for the proposed combination.

SYNNESTVEDT & LECHNER LLP

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The references Drasler et al and Jayarman fail to meet the criteria necessary to establish a prima facie case of obviousness because, when combined, they do not teach or suggest all of the elements recited in Claim 31, and there is no motivation for the proposed combination since both references teach away from applicant's invention.

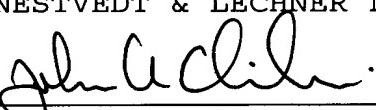
Summary

Applicant has shown in the argument presented above that none of the references teaches or suggests a graft comprising a substrate having a reinforced attachment region defined by a pair of higher tensile strength filamentary members and confined adjacent to an edge of the substrate. The cited references are either irrelevant or teach away from the invention recited in the claims. Applicant contends that the claims, as amended, are allowable and respectfully requests that the application be passed to issue.

Respectfully submitted,

SYNNESTVEDT & LECHNER LLP

By:


John A. Chionchio
Reg. No. 40,954

1101 Market Street, Suite 2600
Philadelphia, PA 19107-2950
Telephone: (215) 923-4466
Facsimile: (215) 923-2189

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Enclosures